DEC - 2 2011 K113245

510(k) Summary

1. Applicant Name and Address

CooperVision, Inc.
6150 Stoneridge Mall Drive
Suite 370
Pleasanton CA 94588

2. Contact

Gwen Sharp
Regulatory Affairs
(925) 621-2457
gsharp@coopervision.com

3. Date Prepared

November 1, 2011

4. Device Identification

Trade Name:	Avaira (*enfilcon A*) Soft (Hydrophilic) Contact Lens
Common Name:	Soft Contact Lens
Classification Name:	Soft (hydrophilic) Contact Lens – Daily Wear; Disposable
Device Classification:	Class II (21 CFR 886.5925)
FDA Material Class:	FDA Group I, Low Water, Nonionic Soft Contact
Product Code:	MVN, LPL

K113245

5. Device Description

The Avaira (enfilcon A) soft contact lens is a Group I, daily wear silicone hydrogel contact lens that is not surface treated and is characterized by a high oxygen permeability (Dk). The lens material, *enfilcon A*, is composed of silicone macromers cross linked with other monomers, incorporating phthalocyanine blue as an integrated, handling tint. A UV blocker is added to reduce the amount of ultraviolet light transmitted into the eye. The lenses are manufactured in spherical, aspherical, toric and multifocal configurations. The Avaira *(enfilcon A)* Soft (hydrophilic) contact lenses are a hemispherical shell. The physical properties and available dimensions are unchanged from predicate 510(k)s.

6. Intended Use

SPHERICAL AND ASPHERICAL:
Avaira (*enfilcon A*) SPHERE and ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

TORIC:
Avaira (*enfilcon A*) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MULTIFOCAL:
Avaira (*enfilcon A*) MULTIFOCAL lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The Avaira (*enfilcon A*) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting systems. The lens may also be prescribed for single-use disposable daily wear.

K113245

7. Predicate Device(s)

Avaira (enfilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear (K071736) cleared January 4, 2008.

8. Characteristics of Substantial Equivalence

The soft contact lenses have the following similarities to the predicate lens that previously received 510(k) clearance:

- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

The modifications to the stability/shelf life protocol include an alternate test method for package integrity and adjusted storage temperatures for the packaged products that will be tested using alternate package integrity test method.

In summary, the enfilcon A soft contact lenses described in this submission are substantially equivalent to the predicate device.

9. Physiochemical Studies

Results from physical, optical and chemical properties were not required as support for this modification to shelf life protocol. Change will not affect physicochemical properties of the lenses.

10. Toxicology Studies

Results from in-vivo and in-vitro studies were not required as support for this modification to shelf life protocol. Change will not affect lenses ability to remain non-toxic and biocompatible with the ocular environment.

K113245

11. Conclusions of Non-Clinical Tests Performed:

- **Physiochemical:**

  The physical, optical and chemical properties of this lens remain unchanged from the unmodified device, and are within established specifications for the lenses.

- **Toxicology:**

  Results from in-vivo and in-vitro studies originally conducted remain valid and verify that the lenses remain non-toxic and are biocompatible with the ocular environment.

12. Clinical Studies

The technical characteristics, formulation, manufacturing, and sterilization processes of this lens are not changing and therefore are equivalent to enfilcon A soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

13. Conclusions

Based on no change to material, no change to manufacturing methods, no change to lens parameters and no change to indicated use, the enfilcon A soft contact lens described in this document are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CooperVision, Inc.
c/o Ms. Gwen Sharp
Global Regulatory Affairs
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588

DEC - 2 2011

Re: K113245
Trade/Device Name: Avaira (enfilcon A) Soft (Hydrophilic) Contact Lenses:
Avaira (enfilcon A) Spherical and Aspherical Soft (Hydrophilic) Contact Lenses for Daily Wear
Avaira (enfilcon A) Toric Soft (Hydrophilic) Contact Lenses for Daily Wear
Avaira (enfilcon A) Multifocal Soft (Hydrophilic) Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL and MVN
Dated: November 01, 2011
Received: November 02, 2011

Dear Ms. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keva Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113245

Device Name: Avaira (*enfilcon A*) Soft (hydrophilic) Contact Lenses

Indications for Use:

SPHERICAL AND ASPHERICAL:
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DAILY DISPOSABLE:
The Avaira (*enfilcon A*) Soft (hydrophilic) Contact Lenses are indicated for single-use disposable wear.

FREQUENT REPLACEMENT:
The Avaira (*enfilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting system.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113245